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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,590	12/28/2000	Ira Herman	TUI-001CP	6511

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/22/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/750,590

Applicant(s)

HERMAN ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 2 is/are allowed.
- 6) ☒ Claim(s) 3-12 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to the "Response to Non-Final Office Action" filed 7 February 2003 (Paper No. 22) in reply to the Office Action mailed 3 July 2002 (Paper No. 19). Claims 1-12 and 20-22 were considered in Paper No. 19. Claims 13-19 and 23-28 were canceled and claim 5 was amended in Paper No. 22. Claims 1-12 and 20-22 are pending and under consideration herein.

Priority

Applicants claim of priority to U.S. Provisional application 60/170,182, filed 10 December 1999, and status as a continuation-in-part of U.S. Patent application 09/733,818, filed 8 December 2000, is acknowledged

Specification

The specification stands objected to for reasons of record in Paper No. 19. In response to the objection for failure to provide accession numbers for the deposited material in the specification, Applicant cites *In re Lundak* 723 F2d. 1216, 227 USPQ 90 (Fed. Cir. 1985) and submits that, pursuant to *In re Lundak*, Applicant has the right to make a deposit of a plasmid containing a nucleic acid sequence encoding bcap73 prior to issuance of the application. Applicant's argument is acknowledged; however, until such time as the specification is amended to include deposit numbers, the objection to the specification will stand. Furthermore, Applicant is reminded that *Lundak* makes clear that any deposited material added to the specification after filing must have been described in the specification at the time of filing with sufficient clarity to

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convey to those of skill in the art that, as of the filing date sought, Applicant was in possession of the invention.

Response to Amendment

Claim Rejections - 35 USC § 112

Claim 3 stands rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement for reasons of record in Paper No. 19 and herein below in the "Response to Arguments".

Claims 4-12 and 20-22 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description for reasons of record in Paper No. 19 and herein below in the "Response to Arguments"

Claims 3, 6-12 and 20-22 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for reasons of record in Paper No. 19 and herein below in the "Response to Arguments".

Claim Rejections - 35 USC § 102

Rejection of claims 5-11 under 35 U.S.C. § 102(b) as anticipated by Wilkin *et al.* is withdrawn in view of the amendments to the claims in Paper No. 22.

Rejection of claims 5-12 under 35 U.S.C. § 102(b) as anticipated by Jacobs *et al.* is withdrawn in view of the amendments to the claims in Paper No. 22.

Rejection of claims 5-11 under 35 U.S.C. § 102(b) as anticipated by Linskens *et al.* is withdrawn in view of the amendments to the claims in Paper No. 22.

Claims 20-22 stand rejected under 35 U.S.C. § 102(b) as anticipated by Wilkin *et al.* for reasons of record in Paper No. 19 and herein below in the "Response to Arguments".

Response to Arguments

Claim Rejections - 35 USC § 112, first paragraph

Claim 3 was rejected under 35 U.S.C. § 112, first paragraph, for lacking enablement based on the deposit requirement. In response, Applicants submit that consideration will be given to whether the specification will be amended to include the ATCC deposit information for the bcap73 molecule when this information becomes available and prior to issuance of the application, if appropriate. Applicant's statement is acknowledged. However, until such time as the claim is amended to include an accession number for a perfected deposit or canceled, the rejection will stand. For reasons set forth herein above, any claims to deposited material that was not adequately described in the originally filed specification will be rejected as new matter.

Claims 4-12 and 20-22 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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With regard to claim 4, Applicant submits that there is sufficient written description in the specification regarding naturally occurring allelic variants to inform a skilled artisan that Applicants were in possession of the claimed invention at the time the application was filed. Applicant cites *The Regents of the University of California v. Eli Lilly and Co.* 43 USPQ2d 1398, 1406 and states that the applicable standard for written description if the instant claims is whether the accompanying specification defines the structural features common to a substantial portion of the genus. Applicant argues that the instant specification satisfies this requirement for the claimed invention because the claimed genus of naturally occurring allelic variants of the present invention is defined by structural features that are described by: the structure of the bcap73 polypeptides and nucleic acid molecules; a teaching that functional allelic variants will typically contain only conservative substitutions of one or more amino acid, deletion or insertion of non-critical residues in non-critical regions of the protein; a teaching of multiple binding domains; a teaching of sequence conservation among bcap73- related family members; and a teaching of a signature pattern in the bovine bcap73 protein. Applicant asserts that the specification describes a genus of naturally occurring allelic variants based on structural features that are common to a substantial portion of the genus.

This argument has been fully considered but is not found persuasive primarily because the claim is directed to a polynucleotide encoding a *naturally occurring* allelic variant of the polypeptide sequence set forth as SEQ ID NO:2. All of the teachings from the specification cited above are attempts to describe the genus of polypeptides that might have the same function as the polypeptide comprising the sequence set forth as SEQ ID NO:2. First, it must be noted that the claim is not limited to a functional allele; therefore, the examples cited clearly do not support the

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large number of non-functional alleles encompassed by the claimed subject matter. Furthermore, there is no description of the mutational sites that exist *in nature* and there is no description of how the structure of the disclosed nucleic acid sequences relate to the structure of any naturally occurring alleles. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is that they are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others. Therefore, the common attributes of the genus are not described and one of skill in the art would conclude that applicant was not in possession of the claimed genus.

With regard to claims 5(a) and (c), and the claims depending therefrom, Applicant traverses the rejection citing Example 14 of the Revised Interim Written Description Guidelines Training Materials, which provides that all members having at least 95% structural identity with the reference polypeptide and catalyzing a disclosed reaction are adequately describe by the disclosure of the reference polypeptide and a method of measuring the functional limitation. Applicant asserts that claim 5(a), directed to a nucleic acid molecule comprising a nucleotide sequence which is at least 85% identical to the entire nucleotide sequence of SEQ ID NO:1 or 3 wherein said nucleic acid molecule encodes a protein having a bcap73 activity, is similarly described by the disclosure of assays for identifying all of the at least 85% identical variants of SEQ NO:1 or 3 and assays that may be used to test whether these variants have a bcap73 activity. Applicant further argues that claim 5(c), directed to a nucleic acid molecule comprising a nucleotide sequence which is at least 55% identical to the entire nucleotide sequence of SEQ ID NO:2 wherein said nucleic acid molecule encodes a protein having a bcap73 activity, is

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adequately described by the disclosed assays for identifying all of the at least 55% identical variants of SEQ ID NO:1 or 3.

These arguments have been fully considered but are not persuasive because the instant claims, unlike the claim described in the cited example, are not limited to a nucleic acid encoding a polypeptide having 95% identity with the disclosed polypeptide and are not limited to a specific function. The polypeptide encoded by the polynucleotide of claim 5(a) might have as little as 85% identity with the disclosed polypeptide, and the polypeptide of claim 5(c) might have as little as 55% identity with the disclosed polypeptide. Thus the genera of nucleic acids claimed in the instant application is much larger and much more diverse than the genus claimed in the example; therefore, the disclosed sequence is less representative of the full scope of claimed sequences. Furthermore, the function of bcap73 activity, as it is set forth in the first paragraph on page 12, is not clearly defined. The specification indicates that bcap73 activity encompasses any function of the bcap73 protein, not limited to a known function, including: association with a bcap73 target molecule, wherein a bcap73 target molecule is circularly defined as a molecule that interacts with bcap73; regulation of subcellular actin distribution or actin function or cell motility or response to tissue injury; or action as an actin binding factor to modulate functions such as subcellular actin distribution changes in cytoskeletal structure, cell motility and response to injury. Thus, claims 5(a) and (c) encompasses any polynucleotide encoding a polypeptide having 85% or 55% identity to SEQ ID NO:2 and having any function that might be directly or indirectly attributed to bcap73 activity whether that function of bcap73 was known or unknown at the time of filing. The claims therefore encompass a genus of nucleic acids encoding polypeptides that are divergent in both structure and function. Clearly, disclosing

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the structure of a single species and a method of determining only a subset of the many functions that the polypeptide encoded by the claimed nucleic acid might have fails to adequately describe the full scope of the genus encompassed by the claims.

With regard to claim 5(b), Applicant's arguments would be persuasive were the claim limited to a nucleic acid molecule comprising a fragment of a nucleic acid consisting of the nucleotide sequence of SEQ ID NO:1 or 3. As the claim is presently limited to a nucleic acid comprising a fragment of a nucleic acid comprising the nucleotide sequence of SEQ ID NO:1 or 3, the claim encompasses fragments other than those set forth as SEQ ID NO:1 or 3 (i.e., those that are comprised beyond the disclosed sequence).

With regard to claim 5(d), Applicant cites Example 15 of the *Interim Guidelines*, which addresses written description for a genus of polynucleotide fragments of a disclosed sequence having the function of antisense inhibitors, and argues that the description of SEQ ID NO:2 defines and limits the structure of any polypeptide fragment such that one skilled in the art would be able to immediately envisage members of the genus embraced by the polypeptide fragments. This argument is not persuasive because, as indicated in the quotation set forth in the response (bridging pages 8 and 9), the finding of adequate written description in Example 15 was based not only on the disclosed sequence but also on the disclosure of the "functional characteristics of the claimed invention". The nucleic acid molecules of claim 5(d) are not limited to having any particular function, and the disclosure provides no information with regard to what function the claimed nucleic acid molecules or polypeptide fragments encoded thereby might have. Therefore, the instant disclosure fails to adequately describe the claimed invention.

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Claim Rejections - 35 USC § 112, second paragraph

Claims 3, and 6-12 and 20-22 as they depend from claim 3, were rejected under 35 U.S.C. § 112, second paragraph, as indefinite in being directed to a biological deposit without supplying a deposit number. Applicant traverses the rejection on the grounds that, pursuant to *In re Lundak (Id.)*, Applicant has the right to make a deposit of a plasmid containing a nucleic sequence encoding bcap73 prior to the issuance of the application. However, until such time as a deposit number is provided, the scope of the claimed subject matter remains indefinite. Therefore, the claims will stand rejected under the second paragraph of 35 U.S.C. § 112.

Claim 22 was rejected on the grounds that the phrase "compound which selectively hybridizes to a nucleic acid" is confusing in its use of the broad term compound. In response, Applicant argues, "it is well-known in the art that compounds, for example, antisense molecules and probes, can selectively hybridize to nucleic acid molecules. Moreover, one of skill in the art at the time of invention would know that molecules that can selectively hybridize to a nucleic acid molecule, such as the nucleic acid molecules of any one of claims 1, 2, 3, 4, or 5, are encompassed by the term 'compound'" (page 10). This argument is not persuasive because, although the Examiner has already conceded that the compound of the claim would encompass nucleic acid molecules, it is unclear what compounds other than nucleic acid molecules would selectively hybridize to the nucleic acid molecules of claims 1-5.

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Claim Rejections - 35 USC § 102

Claims 20-22 were rejected under 35 U.S.C. § 102(b) as anticipated by Wilkin *et al.* In response, Applicant argues that the pending claims are not anticipated by Wilkin *et al.* because Wilkin *et al.* does not teach a fragment which is at least 85% identical to the nucleotide sequence of SEQ ID NO:1 or 3. This argument is not persuasive because the claims do not require a sequence according to the limitations of claims 1-5. The nucleic acid used in the method and comprised in the kit need only be capable of selectively hybridizing with the nucleic acid molecules of claims 1-5. As the nucleic acid molecule taught by Wilkin *et al.* is 83% identical to the sequence set forth as SEQ ID NO:1, it would clearly be capable of selectively hybridizing with nucleic acid molecules which are at least 85% identical to the nucleotide sequence of SEQ ID:1 or 3. Therefore, the claims stand rejected.

*New Grounds Necessitated by Amendment*Claim Rejections - 35 USC § 112

Claims 5-12 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 5(d) has been amended such that it is now directed to a nucleic acid encoding a fragment of the amino acid sequence set forth as SEQ ID NO:2, wherein the fragment comprises at least 20 contiguous amino acid residues. There is no support for a fragment limited to at least 20 contiguous amino acid residues in the original disclosure.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

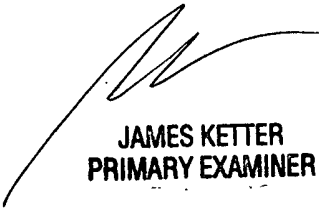
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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April 17, 2003



**JAMES KETTER
PRIMARY EXAMINER**